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May 14, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Health Claims Based on Authoritative Statements
(Docket No. 99N-0554)

Ladies/Gentlemen:

Enclosed for filing in the above-referenced docket are the comments of our client, the National Nutritional Foods Association (NNFA).

These comments were also verbally delivered by Michael Ford, NNFA's Executive Director, at the public meeting held on May 11, 1999.

Sincerely yours,

Charles J. Raubicheck

CJR/dmp
Enclosure

cc (w/encl.): Michael Q. Ford

99N-0554 C10

FDA Public Meeting on Health Claims
Based on Authoritative Statements

Presentation by

MICHAEL Q. FORD
EXECUTIVE DIRECTOR
NATIONAL NUTRITIONAL FOODS ASSOCIATION

On behalf of the National Nutritional Foods Association, I wish to thank FDA for the opportunity to serve as a member of Commenter Panel at today's meeting. As you may know, NNFA is the largest trade association of suppliers and retailers of dietary supplements and natural food products in the country. As such, our members have a vital interest in communicating scientifically-established relationships between nutrients and health-related conditions to American consumers in product labeling. My presentation this morning will focus on five issues concerning FDA's efforts to implement the use of health claims based on authoritative statements of scientific bodies.

First, NNFA supports FDA's proposal to clarify by rulemaking that dietary supplements, as well as conventional foods, are covered by the authoritative statement provisions of the Food and Drug Administration Modernization Act of 1997 (FDAMA). Dietary supplements are also foods, and FDA has applied the health claim standards of NLEA to dietary supplements and conventional foods on an equal basis. It follows that Section 303 of FDAMA, which amends those health claim standards, should extend to supplements.

Secondly, the U.S. Congress has explicitly defined an authoritative statement that can be used to support a health claim in Section 303 of FDAMA. An authoritative statement has four elements: (1) it must be issued as an authoritative statement by a scientific body of the Federal Government responsible for public health protection or nutrition-related research, such as NIH or the National Academy of Sciences; (2) it must be published; (3) it must be currently in effect; and (4) it must be a statement "about the relationship between a nutrient and a disease or health related condition to which the claim refers." These criteria could not be any clearer. Congress has drafted a precise definition which requires no augmentation or amplification, by regulation, guidance or otherwise. NNFA believes that additional criteria which have been mentioned, such as deliberative review by the scientific body and identification of nutrient levels, are already covered by the statutory criteria. For example, an authoritative statement of a scientific body will obviously have been based on a deliberative scientific review by that body, and nutrient levels will have been discussed in the statement itself.

Third, while FDAMA provides that authoritative statements be published by governmental agencies, the private nutrition-related research sector should be considered part of the authoritative statement process. Many of the clinical studies and other data cited in an authoritative statement as grounds for its conclusions will likely have been generated by private research entities, such as medical schools, teaching hospitals, clinics or medical societies. Indeed, such private entities may have received governmental funding for research that is relied upon in an authoritative statement. NNFA encourages the governmental scientific bodies who issue authoritative statements to foster nutrition-related research by resource-intensive private research

institutions. This is bound to further the interests of public health, and, through the authoritative statement mechanism, to provide increased health benefit communications to consumers.

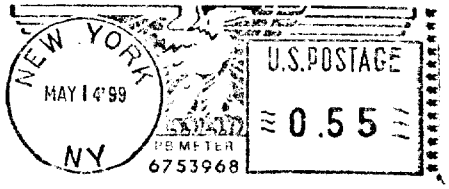
Fourth, NNFA maintains that the "significant scientific agreement" standard for health claims is inextricably linked to FDAMA's authoritative statement standard. This is so because:

(a) by FDAMA's very terms, an authoritative statement can serve as a substitute for a determination by FDA that there is significant scientific agreement supporting a health claim;

(b) in the alternative, FDA can prohibit or modify a health claim based on an authoritative statement if, notwithstanding the conclusion of the statement, the agency decides by regulation that significant scientific agreement for the claim is lacking.

This interplay between the significant scientific agreement and authoritative statement standards will require FDA to take the recent Pearson court decision into account in implementing FDAMA's authoritative statement provisions. Pearson directs FDA to promulgate a concrete definition of the term "significant scientific agreement" for evaluating the validity of health claims. If FDA were to consider prohibiting or modifying a health claim based on an authoritative statement because the agency believes the claim is not based on significant scientific agreement, it cannot do so until it defines the latter term.

Finally, NNFA urges FDA to consider the establishment of a standing Advisory Committee on Dietary Supplements. Where health claims for dietary supplements are involved, such an Advisory Committee would be a valuable resource in helping the agency evaluate whether a given statement is authoritative under the statutory criteria, and in deciding questions of significant scientific agreement. A standing Advisory Committee on Dietary Supplements could also assist FDA in addressing the scientific issues that are likely to continue to arise as FDA carries out its implementation of DSHEA.



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